510(k) Summary

Date Summary Was Prepared: July 20, 2006

AUG - 4 2006

Submitter's Information:

Kendall
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Contact:

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Manager, Regulatory Affairs
Kendall
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Device Trade Name: 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™)

Device Common Name: Catheter, Hemodialysis, Apheresis, Intravascular

Classification Panel: Gastroenterology

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
The Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™) is substantially equivalent to the Kendall Palindrome™ 14.5 Fr Chronic Hemodialysis Catheter with Slotted Symmetrical Tip (K043272) in intended use, materials, physical characteristics, and performance characteristics. The modification attributed to the predicate device is the addition of a silver impregnated sleeve from the hub to the cuff of the catheter to reduce catheter colonization in the subcutaneous tunnel tract. This silver impregnated sleeve is substantially equivalent in intended use and performance characteristics as the legally marketed VitaGuard™ silver impregnated cuff (K861563).

Device Description:
The Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™) has a radiopaque polyurethane shaft with two large inner lumens designed in a "double D" configuration. The distal end of the catheter extends to a symmetrical tip. The proximal end of the catheter shaft contains a polyurethane hub assembly and silicone extension sets. The catheter contains a silver impregnated sleeve permanently bound to the outer surface of the device from the hub to the cuff for the purpose of reducing microbial colonization on the external surface of the catheter in the subcutaneous tunnel tract.

Intended Use:
The Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™) is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. Catheters greater than 40 cm implant length are indicated for femoral insertion. The performance of the silver impregnated sleeve in reducing colonization on the catheter surface for up to 30 days was supported by bench and animal testing.

Performance Data:
Performance data for the Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™) is compared to that of the predicate catheter identified in this 510(k) summary. Results of verification / validation demonstrate that the modified device is substantially equivalent to the legally marketed device.

Safety and Effectiveness:
Testing conducted on the proposed device confirmed that the presence of the silver impregnated sleeve did not affect the safety and catheter performance of the device. In addition to the standard tests applicable to intravascular catheters published by ASTM, ISO, and KDOQI guidelines, testing specific to the silver impregnated sleeve included:

- Biocompatibility testing at highest level of silver loading
- Determination of total silver amount in sleeve to confirm safety versus toxicity and exposure limits
- Silver elution to demonstrate controlled release
- In-vitro studies demonstrating a significant reduction, between 2.1 and 5.5 $\log_{10}$ reductions, in the amount of microbial colonization on the silver impregnated sleeve after repeated challenges with *Staphylococcus aureus*, Coagulase-negative Staphylococcus, *Candida albicans*, and *Escherichia coli* (all clinical isolates).
- In-vivo studies demonstrating a significant reduction, between 2.5 and 4.9 $\log_{10}$ reduction in the amount of microbial colonization on the silver impreganted sleeve after repeated subcutaneous inoculation of *Staphylococcus aureus* (clinical isolate) in a rabbit infection model.

The results of these tests demonstrate that the Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™) is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

Mr. Keith Martin
Manager, Regulatory Affairs
Kendall
A Division of Tyco Healthcare Group LP
15 Hampshire Street
MANSFIELD MA 02048

Re: K060972
Trade/Device Name: Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: July 20, 2006
Received: July 21, 2006

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains povidone iodine swabs which are subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-3150. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive, Abdominal
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060972

Device Name:

Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™)

Indications for Use:

The Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™) is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. Catheters greater than 40 cm implant length are indicated for femoral insertion. The performance of the silver impregnated sleeve in reducing colonization on the catheter surface for up to 30 days was supported by bench and animal testing.

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagmore

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060972